EXHIBIT B

Letter of David A. Sierleja, First Assistant U.S. Attorney, to Hon. Dan A. Polster, U.S.D.J., in *In re Nat'l Prescr. Opiate Litig.*, No. 1:17-md-2804 (N.D. Ohio) (Jan. 30, 2018)

U.S. Department of Justice

United States Attorney
Northern District of Ohio

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January 30, 2018

The Honorable Dan A. Polster
United States District Court Judge, Northern District of Ohio
Carl B. Stokes United States Court House
801 W. Superior Avenue, Courtroom 18B
Cleveland, Ohio 44113-1837

Re: *In Re: National Prescription Opiate Litigation.*
N.D. Ohio Case No. 1:17-MD-2804

Dear Judge Polster:

The United States Department of Justice is in receipt of your e-mail dated January 19, 2018, in which you requested disclosure of official Department of Justice information. Specifically, you asked for the following information from the United States Drug Enforcement Administration ("DEA"):

1. How is the annual nationwide quota of prescription opioids determined?
   a. Do the manufacturers have input?
2. How is that quota administered? For example, is each manufacturer given a specific number of pills it can make?
   a. Is there any regulation of how many pills can be sold in a specific geographic area?
3. How is the ARCOS database generated?
   a. What information is each drug manufacturer and distributor required to transmit?

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b. What does DEA do with this database? What resources are allocated to analyzing the data?

4. What type of tracking of pills do the regulations require manufacturers and distributors to do?

5. What constitutes a "suspicious" transaction or order that a distributor is required to report?

   a. What is the magnitude of suspicious reports that come to DEA in a given month? A few, hundreds, thousands?

   b. What does DEA do with these suspicious reports? How many agents are tasked with tracking them?

6. Who are the principal manufacturers of generic opioids?

Federal regulations govern the disclosure of official Department of Justice information by federal employees and agencies, including the DEA. *See* 28 C.F.R. § 16.21-.29. The regulations apply, *inter alia*, in situations such as this, where the United States is not a party to the proceeding. Under those regulations, current and former DEA employees are prohibited from disclosing official information absent express authorization from the Department of Justice. 28 C.F.R. § 16.22(a).

The Supreme Court has long recognized the authority of federal agencies to regulate the disclosure of information by their employees. *U.S. ex rel. Touhy v. Ragen*, 340 US. 462 (1951). In *Touhy*, the United States Supreme Court held that a federal employee could not be held in contempt for refusing to produce subpoenaed documents, where his refusal was based on regulations prohibiting the disclosure of official information without prior authorization. *Id.* at 468. Nor did such regulations invade the authority of the Courts to determine the admissibility of evidence. *Id.* at 468-70.

Pursuant to 28 C.F.R. § 16.22, I am the official responsible for consulting with the DEA and authorizing any disclosure in response to your request. Federal regulations require me to consider whether disclosure is appropriate under the applicable rules of procedure and law concerning privilege. 28 C.F.R. § 16.26(a). The release of official information is prohibited if disclosure would:

1. Violate a specific statute or regulation;

2. Reveal classified information;

3. Reveal a confidential source or informant;

4. Reveal investigative techniques or investigatory records compiled for law enforcement purposes; or

5. Reveal trade secrets without the owner's consent.

28 C.F.R. § 16.26(b).

After carefully considering your request and the above factors, I have determined that providing information in the form of written responses to your inquiries is in the public interest. Indeed, I believe that providing the information is consistent with the Department of Justice's priority to attack the devastating opioid crisis that is ravaging families and communities across America. The Department has taken a number of steps to stem the tide of this urgent problem, by, among other things, prosecuting those who overprescribe opioid painkillers and those who flood our streets with drugs. The Department has launched a pilot program to utilize data and focus prosecutions on opioid-related health care fraud including pill mill schemes and pharmacies that unlawfully divert or dispense prescription opioids for illegitimate purposes. To help combat the opioid crisis, the Department also has provided millions of dollars in grants to state and local law enforcement agencies to take heroin, methamphetamines, cocaine, and other illicit and diverted drugs off our streets. Accordingly, I hereby authorize Demetra Ashley, Acting Assistant Administrator, Diversion Control Division, DEA, to provide written responses to your inquiries set forth above. The responses are attached hereto as Exhibit A.

The responses are limited to publicly available information in accordance with the privileges listed above and any other governmental privileges, including but not limited to the attorney-client privilege and the deliberative process privilege. Please note that I am unable to authorize disclosure of potentially responsive information that would disclose law-enforcement-sensitive information; investigative records or techniques; information protected under the Trade Secrets Act; confidential or proprietary business information, or information protected by the Privacy Act, including, but not limited to, personally identifiable information of individual registrants who report information to DEA through ARCOS.

Sincerely,

DAVID A. SIERLEJA
First Assistant United States Attorney
Northern District of Ohio
Acting Under Authority Conferred by 28 U.S.C. § 515

Exhibit A

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

To: The Honorable Dan Aaron Polster, United States District Court Judge

From: Demetra Ashley, Acting Assistant Administrator, Diversion Control Division

Subject: Responses provided pursuant to authorization under 28 C.F.R. § 16.21-.29

Date: January 30, 2018

Introduction

The following written responses are provided by the Drug Enforcement Administration pursuant to authorization under 28 C.F.R. § 16.21-.29.

1. How is the annual nationwide quota of prescription opioids determined?

a. Do the manufacturers have input?

DEA establishes three types of quotas: aggregate production quotas, individual manufacturing quotas, and procurement quotas. DEA sets quotas for each basic class of controlled substance in schedules I and II, and for ephedrine, pseudoephedrine, and phenylpropanolamine. Procedural requirements for establishing quotas, inventory allowance, and adjustments to quotas and related issues are governed by 21 U.S.C. § 826 and 21 C.F.R. Part 1303.

Aggregate production quotas (APQs) are governed by 21 U.S.C. § 826(a) and the implementing regulations codified at 21 C.F.R. §§ 1303.11 and 1303.13. APQs are established to provide for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. In setting the APQ, the regulations provide that the Administrator must consider:

1. Total net disposal of the class by all manufacturers during the current and two preceding years;

2. Trends in the national rate of net disposal of the class;

3. Total actual (or estimated) inventories of the class and of all substances manufactured from the class, and trends in inventory accumulation;

4. Projected demand for such class as indicated by procurement quotas requested pursuant to 21 C.F.R. § 1303.12; and

5. Other factors affecting medical, scientific, research and industrial needs in the United States and lawful export requirements, as the Administrator finds relevant. These factors can include: changes in the currently accepted medical use in treatment with the class or the substances which are manufactured from it; the economic and physical availability of raw materials for use in manufacturing and for inventory purposes; yield and stability problems; potential disruptions to production (including possible labor strikes); and recent unforeseen emergencies such as floods and fires.

Manufacturers have input into the setting of the national production quotas by timely commenting to the published *Federal Register* Notice and by supplying business confidential and proprietary information on their quota application requesting to manufacture specific controlled substances. 21 C.F.R. §§ 1303.11(c), 1302.12, 1303.22.

2. **How is that quota administered? For example, is each manufacturer given a specific number of pills it can make?**

   a. **Is there any regulation of how many pills can be sold in a specific geographic area?**

Manufacturing quotas are issued to each person registered to manufacture a basic class of controlled substance listed in schedules I and II, who applies for a manufacturing quota, to authorize that person to manufacture during the next calendar year a quantity of that basic class of substance. *See* 21 U.S.C. § 826(c); 21 C.F.R. §§ 1303.21- 1303.27.

The CSA directs DEA, in fixing manufacturing quotas, to determine the manufacturer's estimated disposal, inventory, and other requirements for the calendar year. 21 U.C.S. § 826(c). DEA is required to consider the manufacturer's current rate of disposal, the trend of the national disposal rate during the preceding calendar year, the manufacturer's production cycle and inventory position, the economic availability of raw materials, yield and stability problems, emergencies such as strikes and fires, and other factors.

Procedures for establishing manufacturing quotas are described in 21 C.F.R. § 1303.23. The Administrator allocates to each applicant who is currently manufacturing a basic class of controlled substance a quota equal to 100 percent of the applicant's estimated net disposal for the next calendar year, adjusted by the amount necessary to increase or reduce the applicant's inventory on December 31 of the current year to his estimated inventory allowance for the next calendar year, and by any other factors the Administrator deems relevant, including: trends of (and recent changes in) his and the national rates of net disposal; his production cycle and current inventory position; the economic and physical availability of raw materials for use in manufacturing and for

inventory purposes; yield and stability problems; potential disruptions to production (including possible labor strikes); and recent unforeseen emergencies such as floods and fires.

Adjustments (increases or decreases) to manufacturing quotas are addressed in *id.* §§ 1303.25 and 1303.26.

3. How is the ARCOS database generated?

a. What information is each drug manufacturer and distributor required to transmit?

DEA's external website explains the role of the ARCOS database in the agency's law enforcement mission:

> ARCOS is an automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level—hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions. Included in the list of controlled substance transactions tracked by ARCOS are the following: All Schedule I and II materials (manufacturers and distributors); Schedule III narcotic and gamma-hydroxybutyric acid (GHB) materials (manufacturers and distributors); and selected Schedule III and IV psychotropic drugs (manufacturers only).

Pursuant to the Controlled Substances Act (CSA), manufacturers and distributors (registrants) of certain controlled substances must report the manufacture, sale, purchase, loss, or other disposition of such controlled substances to DEA. 21 U.S.C. § 827. Registrants self-report this information to DEA through ARCOS.

DEA collects ARCOS business transactions between entities that handle controlled substances from manufacturers or distributors down to the point of retail level registrants. Records include copies of controlled substances inventories, drug codes, deletion and adjustment reports, form 222s, and include the date of the transaction, the name, quantity and strength of the substances purchased, the parties to the transaction, and the DEA registrant numbers. Over the course of the past eleven years, registrants have reported hundreds of millions of transactions. For example, in 2016 alone, registrants reported nearly 80 million ARCOS transactions. This information is self-reported by registrants, which DEA internally verifies before use. To this end, a unit within the Diversion Division's Pharmaceutical Investigations Section performs quality control reviews of ARCOS data and then uses validated ARCOS data to detect anomalies and identify leads.

The data reported by registrants to DEA is treated as privileged and confidential commercial information. The information that registrants report to ARCOS is often proprietary, as it includes information about the registrant's commercial sales and its customer base. Because of the sensitive nature of the information, DEA does not permit a registrant to access another registrant's reported

transactional data in ARCOS. Disclosure of this company-specific information could cause competitive harm to the DEA registrant from whom it was obtained and therefore is not permitted to be disclosed to the public.

The information reported through ARCOS is summarized into reports which give investigators in Federal and state government agencies information that can be used to identify the diversion of controlled substances into illicit channels of distribution. The information on drug distribution is used throughout the United States by U.S. Attorneys and DEA investigators to strengthen criminal cases in the courts. DEA's authorization to operate ARCOS is conditioned on numerous privacy and information security protections DEA ARCOS Privacy Impact Assessment (PIA) includes a requirement that access to ARCOS only be given to authorized DEA personnel. *See* DEA ARCOS Privacy Impact Assessment (PIA), Section 8.0, Technical Access and Security (https://www.dea.gov/FOIA/pia_docs/arcos_2%208_8_06.pdf). The PIA implements the requirements of the E-Government Act of 2002, the Federal Information Security Management Act of 2002 (FISMA), and the White House Office of Management and Budget (OMB) Circular A-130.

JUSTICE/DEA-003 is the Privacy Act system of records in which ARCOS information is contained within. *See* 69 Fed. Reg. 51104-02. Release of the personally identifiable information of individual registrants without their consent would violate the Privacy Act. Therefore DOJ objects to the production thereof under its *Touhy* Regulations (28 C.F.R. § 16.26 (b)(1)). Disclosure would improperly reveal trade secrets without the owners' consent and therefore DOJ objects to the production thereof under its *Touhy* Regulations (*Id.* § 16.26 (b)(5). Production of this data would reveal specific details regarding the scope and breadth of their market share which is likely to cause manufacturers and distributors substantial competitive harm. In Freedom of Information Act litigation, registrants have articulated the competitive harm that would result from the release of this information in several ways. For example, registrants have expressed concern that ARCOS information, if made publicly available, could be used by competitors to determine market share and sales trends in specific areas and would enable competitors to target existing customers and attempt to take away business. For this reason, registrants have repeatedly asserted that they rely on DEA to protect the confidential business information that they report to DEA through ARCOS

The Eighth Circuit found arguments such as this persuasive, holding that a release of ARCOS information would likely cause substantial competitive harm to the registrants. *Madel v. DEA*, 784 F.3d 448 (8th Cir. 2015). Consequently, DEA has entered into binding settlement agreements with registrants like McKesson, agreeing that ARCOS information is confidential and that notice and opportunity to respond would be provided before any release. *See, e.g.*, https://www.justice.gov/opa/press-release/file/928476/download. Additionally, DEA is concerned that release of this information without consent from registrants may violate the Trade Secrets Act, 18 U.S.C. § 1905.

b. What does DEA do with this database? What resources are allocated to analyzing the data?

ARCOS is an important tool in both DEA's law enforcement and regulatory missions. The CSA authorizes the Attorney General to "cooperate with local, State, tribal, and Federal agencies concerning traffic in controlled substances and in suppressing the abuse of controlled substances." 21 U.S.C. § 873(a). Moreover, pursuant to § 873(a)(1), the Attorney General may "arrange for the exchange of information between governmental officials concerning the use and abuse of controlled substances." Similarly, under § 873(a)(6)(C), the Attorney General may "assist State, tribal, and local governments in suppressing the diversion of controlled substances from legitimate medical, scientific, and commercial channels by…establishing cooperative investigative efforts to control diversion." The Attorney General has delegated this authority to the DEA Administrator. 28 C.F.R. § 0.103(a)(1) and (2) (Administrator may "release information obtained by DEA and DEA investigative reports to Federal, State, and local prosecutors, and State licensing boards, engaged in the institution and prosecution of cases before courts and licensing boards related to controlled substances.") Consistent with these authorities, DEA shares ARCOS data with its state law enforcement and regulatory counterparts who have a need to know and are operating in coordination with DEA for investigative purposes.

DEA cannot otherwise disclose the requested information under DOJ's *Touhy* regulations (*Id.* § 16.26(b)(5)) to the extent disclosure would reveal investigatory records compiled for law enforcement purposes, and would interfere with enforcement proceedings. *See also* 40 Op. Att'y Gen. 45, 56 (1941) ("it is the position of the Department . . . that all investigative reports are confidential documents of the executive departments of the Government. . . and that congressional or public access to them would not be in the public interest…").

4. What type of tracking of pills do the regulations require manufacturers and distributors to do?

As explained above, the CSA requires manufacturers and distributors to report the manufacture, sale, purchase, loss, or other disposition of certain controlled substances to DEA. *See e.g.*, 21 U.S.C. § 827 and 21 C.F.R. Part 1304 (reporting requirements); and 21 U.S.C. § 828 and 21 C.F.R. Part 1305 (written order requirements); (Records and Reports of Registrants). The manufacturers (bulk and dosage form) and distributors must report every acquisition / distribution transaction for Schedule I and Schedule II substances and Schedule III narcotics and on GHB products in Schedule III to ARCOS every quarter. The acquisition / transaction reports from are product specific and are listed by the Food and Drug Administration's National Drug Code System (NDC) number, which uniquely identifies a product.

It is also important for the Court know what information the DEA does not possess. The various states have established prescription drug monitoring programs (PDMP). These are electronic databases to which pharmacies must report prescriptions for controlled substances. With access to this information, the DEA could more readily identify physicians and other prescribers who are writing medically unnecessary prescriptions, and stop them. The Centers for Disease Control and Prevention website contains an informative discussion about the usefulness of PDMP data at https://www/cdc/gov/drugoverdose/pdmp/states.html. However, despite DEA's repeated

efforts, many states have refused DEA access to PDMP data, except on a limited basis through case-specific subpoena, because of policy or legal restrictions.

5. What constitutes a "suspicious" transaction or order that a distributor is required to report?

Although manufacturers and distributers of controlled substances are commercial enterprises, they must operate in the public's interest. 21 U.S.C. § 823(a) and (b) (When determining whether to register an applicant to manufacture or distribute a schedule I or II controlled substance, the DEA Administrator must make a public interest determination.) One factor the Administrator considers is the applicant's maintenance of effective controls to guard against the diversion of controlled substances. *Id.* § 823(a)(1) and (b)(1).

To determine whether a registrant has established effective controls against diversion, the Administrator uses the security requirements codified at 21 C.F.R. §§ 1301.72-1301.76. *Id.* § 1301.71(a). One such requirement is the duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." *Id.* § 1301.74(b). "Suspicious orders include orders of unusual size, orders deviating from a normal pattern, and orders of unusual frequency." *Id.*

An effective suspicious order system enables the registrant to uncover and prevent the diversion of controlled substances. For an informative analysis of a registrant's obligation to detect and prevent suspicious orders, we refer the Court to the DEA Decision and Order in *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55418 (September 15, 2015). By this Decision and Order, which was upheld by the District of Columbia Circuit in Masters Pharmaceutical, Inc., v. DEA, 861 F.3d 206 (D.C. Cir. 2017), the DEA revoked the registration of a distributer of controlled substances because it "shirked its legal obligation to report suspicious orders for controlled substances." *Id.* 861 F.3d at 212.

DEA regulations further require the registrant to "inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

a. What is the magnitude of suspicious reports that come to DEA in a given month? A few, hundreds, thousands?

We first must note that registrants must file suspicious order reports for all controlled substances, not just opioids. 21 C.F.R. § 1301.74. Therefore, a gross listing of suspicious order reports does not necessarily give one an insight into the diversion of opioids.

DEA regulations require registrants to submit suspicious order reports to their local DEA Division office. However, when a registrant is the subject of a DEA enforcement action that is resolved through a Memorandum of Agreement (MOA) between the registrant and the DEA, the MOA typically requires the registrant to submit its suspicious order reports to DEA Headquarters. For calendar year 2017, six DEA registrants reported 226,931 suspicious orders to DEA Headquarters, with one registrant accounting for nearly 85% of those reports (192,252), a second for nearly 14% (33,999), and the remainder for less than 1%.

Suspicious order reports sent to DEA Headquarters are submitted through an electronic database. The DEA was able to readily sort these electronic records for individual suspicious orders. The same is not true for suspicious order reports filed with the Division offices. This is because suspicious orders are not reported electronically to the Division Offices. They can be filed, for example, by letter, email or fax. And they can be filed periodically and report multiple transactions. Therefore, the DEA is unable to timely provide an estimate of the average number of suspicious *transactions* reported to the Division offices. With that caveat in mind, a poll of the 22 Division offices revealed that registrants submitted approximately 30,300 suspicious order reports to the DEA division offices during calendar year 2017.

b. What does DEA do with these suspicious reports? How many agents are tasked with tracking them?

The DEA is unable to provide a detailed response to this question for two reasons. First, suspicious order reports are filed in the DEA's 22 Division Offices throughout the United States, and the investigative use of those reports in the field depend on the judgement, policies and priorities of each Division's Special Agent in Charge and Diversion Program Manager. Second, even if we could survey the 22 Divisions to learn how they are currently using the reports, a detailed response to this question could reveal sensitive DEA investigative techniques.

However, by way of example, DEA registrants are subject to scheduled DEA investigations, which include a review the effectiveness of a registrant's diversion controls, to include its suspicious order reporting system. The DEA also uses suspicious order reports as leads to trigger investigations into doctors, pharmacies or other distributors. In addition, the DEA uses suspicious order reports to corroborate leads received from other sources, such as a complaint that a doctor is writing medically unnecessary prescriptions.

6. Who are the principal manufacturers of generic opioids?

The DEA does not generally correlate ARCOS data to distinguish between brand and generic formulations. Therefore, in order to timely answer the Court's questions as completely as possible, we are proving information for the three opioids that are most subject to abuse, whether dispensed

under a brand name or as a generic. Those opioids are Oxycodone, Hydromorphone and Hydrocodone.

For each of those opioids, we have listed the top 10 manufacturers by volume of production for calendar year 2017. There are only 9 companies in Oxycodone and Hydrocodone lists because one company in both lists has 2 DEA registrations, and therefore counts as 2 separate manufacturers; and there are only 8 companies in the Hydromorphone list because 2 companies have dual registrations. In addition, the companies are listed in random order to protect from disclosure proprietary market share information.

OXYCODONE

Warner Chilcott Company, LLC
Vintage Pharmaceuticals, LLC
KVK-TECH, Inc.
Aorolife Pharma, LLC
Amneal Pharmaceuticals, LLC
Norwich Pharmaceuticals, Inc.
Mallinckrodt, LLC
Sun Pharmaceutical Industries, Inc.
Purdue Pharmaceuticals, L.P.

HYDROMORPHONE

ALZA Corporation
Mallinckrodt, LLC
Paddock Laboratories, LLC
West-Ward Pharmaceuticals Corp.
Aurolife Pharma, LLC
AndersonBrecon, Inc.
Lannett Company, Inc.
Halo Pharmaceutical, Inc.

HYDROCODONE

Novel Laboratories, Inc.
Halo Pharmaceutical, Inc.
Sun Pharmaceutical Industries, INC.
Mallinckrodt, LLC
Warner Chilcott Company, LLC
Aurolife Pharma, LLC
Tris Pharma, Inc.
Amneal Pharmaceuticals, LLC
Vintage Pharmaceuticals, LLC